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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Oleg Iliich Epshtein

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Kaplan Gilman & Pergament LLP

1480 Route 9 North

Woodbridge, NJ 07095

EXAMINER

PAK, MICHAEL D

ART UNIT

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1646

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01/07/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/522,651	Applicant(s) EPSHTEIN ET AL.	
	Examiner Michael Pak	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3 and 5-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3 and 5-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 16, 2009 has been entered.

Response to Amendment

2. Amendment filed November 16, 2009 has been entered. Claims 3 and 5-10 are pending. Claims 1-2, 4 are cancelled.

3. Applicant's arguments filed November 16, 2009, have been fully considered but they are not found persuasive.

4. The Declaration of Dr. Oleg I Epstein under 37 CFR 1.132 filed October 29, 2009 is insufficient to overcome the rejection of claims 3 and 5-10 based upon 35 USC 112 second paragraph as set forth in the Office action below because for the reason set forth in the rejections below.

5. The Declaration of Vasilij Nikolayevich Nikolayev under 37 CFR 1.132 filed October 29, 2009 is insufficient to overcome the rejection of claims 3 and 5-10 based upon 35 USC 102 as set forth in the Office action below because for the reason set forth in the rejections below.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 3 and 5-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims recite or encompass the term “homeopathically potentized form” which is ambiguous and confusing because the metes and bounds of the term is not clear. It is not clear when a compound is homeopathically potentized form because it does not appear to be different from the cited reference forms.

Applicants argue that the Declaration of . Oleg I Epstein and Vasilij Nikolayevich Nikolayev under 37 CFR 1.132 provides evidence that one skilled in the art are aware of the term. However, the it is not clear where the metes and bounds of when a material is a homeopathically potentized form or at such low dilution where there are no products

present. It is not clear to all skilled in the art that such form is clear. Goldacre (Lancet, 2007) disclose that homeopathy produced no statistically significant benefit over placebo. The state of the art is such that it is not clear what the product is that is giving the placebo effect.

7. Claims 3 and 5-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims encompass an antibody which is homeopathically potentized form. However, the essential feature of the invention is not clear because the structure which makes an antibody homeopathically potentized is not disclosed. Using the disclosure one of skilled in the art cannot envision the homeopathically potentized molecules of the claimed antibody molecules for the treatment. The claims encompass a form or structure which cannot be described in the specification. The antibody is diluted and becomes homeopathically potentized. The genus of molecules which is homeopathically potentized is not clear. *University of California v. Eli Lilly and Co.* (CAFC) 43 USPQ2d 1398 held that a generic claim to human or mammalian when only the rat protein sequence was disclosed did not have written description in the specification. If one skilled in the art cannot envision the generic claim from the specific example then it lacks written description. Homeopathically potentized antibody cannot

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be envisioned by one skilled in the art. The declarations present opinions of one skilled in the art of homeopathy that the specification discloses homeopathic potentized antibody. However, the state of the art is such that there appears to be a division between the homeopathy artisan and non-homeopathy artisans. Goldacre (Lancet, 2007) disclose that homeopathy produced no statistically significant benefit over placebo. The state of the art is such that one cannot envision what the product is that is giving the placebo effect.

8. Claims 3 and 5-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the antibody such as those disclosed in Le et al., does not reasonably provide enablement for a homeopathically potentized form of antibody. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The first paragraph of § 112 requires that the patent specification enable "those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation." Genentech, Inc. v. Novo Nordisk AIS, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting In re Wright, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)); see also In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). ("[T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art."). Whether making and using the invention would have required

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undue experimentation, and thus whether the disclosure is enabling is a legal conclusion based upon several underlying factual inquiries. See In re Wands, 858 F.2d 731, 735, 736-37, 8 USPQ2d 1400, 1402, 1404 (Fed. Cir. 1988). As set forth in Wands, the factors to be considered in determining whether a claimed invention is enabled throughout its scope without undue experimentation include the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Likewise, in Amgen Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991), the court affirmed the holding of invalidity of claims to analogs of the EPO gene under § 112 for lack of enablement where applicants had claimed every possible analog of the EPO gene but had disclosed only how to make EPO and a very few analogs. "[D]espite extensive statements in the specification concerning all analogs of the EPO gene that can be made, there is little enabling disclosure of the particular analogs and how to make them There may be many other genetic sequences that code for EPO-type products. Amgen has told how to make and use only a few of them and is therefore not entitled to claim all of them." *Id.*, 927 F.2d at 1213-14, 18 USPQ2d at 1027.

Claims encompass a a homeopathically potentized form of antibody. However, one skilled in the art cannot make and use homeopathically potentized form of antibody for treatment. The state of the art is such that one skilled in the art prior to the time of

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the invention found that homeopathically potentized form are no better than placebo (Goldacre (Lancet, 2007)). Goldacre (Lancet, 2007) disclose that homeopathy produced no statistically significant benefit over placebo. The amount of direction provided in the specification is limited to diluting TNF antibodies. One skilled in the art cannot discern where the product is produced which results in a treatment which is different from placebo. One skilled in the art would require empirical experimentation in order to determine the difference between placebo effect and the treatment due to the potentized homeopathically form. In view of the extent and the unpredictability of the experimentation required to practice the invention as claimed, one skilled in the art could not make the invention without undue experimentation.

Therefore, based on the above Wands analysis, a preponderance of the evidence supports a conclusion that one skilled in the art would not have been enabled to make and use the claimed invention without undue experimentation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 3 and 5-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Le et al. (US 5,698,195).

Le et al. disclose anti-TNF antibodies used for treatment of rheumatoid arthritis (columns 34-38). Le et al. teach numerous method of therapeutic administration with different dosages (column 36).

The term “homeopathically potentized antibodies” is not defined and thus the antibodies of Le et al. inherently comprises such properties. The homeopathic dilution terms are relative terms whose metes and bounds cannot be determined since the original concentration prior to dilution is not known. Thus, the dilution term is met by the concentration disclosed by Le et al. In cases where the dilution does not contain the antibody, the undiluted solutions of Le et al. anticipates the claim limitation.

Applicants argue that antibodies are highly dilute and thus cannot be met by the teachings of Le et al. However, the terms are relative term whose final concentration is not clear as discussed in the above rejections for 35 USC 112 paragraph 2. Furthermore, Le et al. discloses the different doses (column 36).

Applicants argue that Le et al. does not disclose the “homeopathically activated form”. However, the antibody inherently has the “homeopathically activated form”.

Applicants argue that one skilled in the art do not believe that the Le et al. reference contains homeopathically potentized antibody by declarations. However, there appears to be different groups of one skilled in the art with different opinions. Goldacre (Lancet, 2007) disclose that homeopathy produced no statistically significant benefit over placebo.

Applicants argue that a prima facie case has not been made for inherency. However, the claimed compound starting material is the same as the antibody of Le et

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al. The subsequent dilution is taught by Le et al. The dilutions without antibody because of the claim limitation to extreme dilutions is met by the product by process limitation where the non-antibody containing solutions of Le et al.

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak whose telephone number is 571-272-0879. The examiner can normally be reached on 8:00 - 2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Michael Pak/
Primary Examiner, Art Unit 1646